DEPARTMENT OF HEALTH & HUMAN SERVICES HFA-305 Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 28 1999

Eve E. Bachrach, Esq.
Vice President, Deputy General Counsel,
and Secretary
Consumer Healthcare Products Association
1150 Connecticut Avenue, N.W., 12th Floor
Washington, DC 20006

Re: Docket No. 97P-0233
Comment No. CP1

Dear Ms. Bachrach:

The enclosed letter to Dr. V. Annette Dickinson, Ph.D., of the Council for Responsible Nutrition, responds to the above referenced citizen petition jointly submitted by Dr. Dickinson and you on June 10, 1997. This petition concerns the lead tolerance levels for calcium supplements and calcium-containing antacids. Any future response to the Council for Responsible Nutrition pertaining to this petition will also be sent to you.

Sincerely yours,

Linda M. Katz, M.D., M.P.H.
Deputy Director
Division of OTC Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and
Research

Enclosures

97P-0233

LET 3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 28 1999

V. Annette Dickinson, Ph.D.
Director of Scientific and Regulatory Affairs
Council for Responsible Nutrition
1300 - 19th Street, N.W., Suite 310
Washington, DC 20036

Re: Docket No. 97P-0233
Comment No. CP1

Dear Dr. Dickinson:

We refer to your citizen petition dated June 10, 1997, on behalf of the Council for Responsible Nutrition, and the Nonprescription Drug Manufacturers Association. The petition requests that FDA maintain the current system for establishing lead limits for food and drug ingredients and refrain from adopting a uniquely low lead limit for calcium ingredients used in dietary supplements and calcium-containing antacids.

At this time, the agency is not adopting new lower lead limits for calcium-containing drug products. Therefore, to this extent, your petition is granted.

However, FDA supports the concept that lead levels of calcium-containing products be as low as practicable. Therefore, FDA is actively investigating the feasibility of establishing lower limits of lead in calcium-containing products (see attached letter of March 11, 1999, from Yana Ruth Mille, Compendial Operations Staff, CDER, to Joseph G. Valentino, J.D., of the United States Pharmacopeial Convention, Inc. (USP)).

If you have any questions regarding the petition, please refer to the docket number and comment number above, and submit all inquiries, in triplicate, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Sincerely yours,

for Dennis E. Baker
Associate Commissioner
for Regulatory Affairs

Enclosure

cc: Eve E. Bachrach, Esq.
Consumer Healthcare Products Association

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

HFD-500
COTKLAN

MAR 11 1999

Joseph G. Valentino, J.D.
Senior Vice President and General Counsel
The United States Pharmacopeial
Convention, Inc.
12601 Twinbrook Parkway
Rockville, MD 20852

REF: 2-99-002-M

Dear Dr. Valentino:

This letter is in reference to the issue of lead levels in calcium-containing antacid drug products. FDA supports the lowest possible lead levels in calcium-containing products. In response to a December 8, 1998, inquiry from CDER's Division of Over-the-Counter Drug Products (DOTCDP), Ms. Susan S. Fiering, Esq., of California's Department of Justice provided us with additional information pertaining to the reduction of lead levels in calcium-containing drug products. (See enclosed letter of January 13, 1999, which summarizes the information provided by Ms. Fiering.)

We are aware of an April 22, 1998, letter from you to Dr. Yetley in which you wrote that, at an April 14, 1998, meeting of the USP Subcommittee on Nonprescription Drugs and Nutritional Supplements, the Subcommittee noted the limitations in analytical methodology which need to be considered especially if the methodology is to be used for regulatory purposes. Finally, you stated that the Subcommittee would, at some future time, consider "an alternative analytical method capable of determining lead content at very low levels, along with a lower practical limit." We urge you to investigate acceptable analytical methods for the determination of smaller amounts of lead in calcium-containing products. For your information, I have also attached a copy of the Consent Judgement in People v. Warner Lambert, et al, which includes the graphite furnace and the ICP-MS methods used in California to analyze lead levels in calcium-containing products. We would appreciate the USP Subcommittee's review of any analytical methods that may be used to establish a lower USP standard for lead in calcium-containing products.

We hope these comments will be helpful to the Nonprescription Drugs and Nutritional Supplements Subcommittee. Please feel free to contact me at 301-594-0104 or Ms. Helen Cothran (301-827-2287), the contact person for this topic in DOTCDP, if there are any questions. Use of the reference number provided above on any ensuing correspondence would be appreciated.

Sincerely yours,

Yana Ruth-Mille

Yana Ruth Mille
Chief
Compendial Operations Staff, HFD-354
Office of Pharmaceutical Science
Center for Drug Evaluation & Research

Enclosures (2)

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: SEP 2 9 1999

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 97P-0233

TO: Dockets Management Branch, HFA-305

☒ The attached material should be placed on public display under the above referenced Docket No.

☒ This material should be cross-referenced to Comment No. CP1

Charles J. Ganley, M.D.

Attachment